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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER
EPPERSON, JON D

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	
Office Action Summary	09/804,481	GRAAF ET AL.	
File Copy	**Examiner**	**Art Unit**	
	Jon D Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The fax number is (703) 308-4315. A fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Andrew Wang, Supervisory Patent Examiner, at (703) 306-3217. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Please Note: The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, drawn to a product described as a "recombinant vector comprising isolated DNA encoding a snRNA", classified in class 536, subclass 23.1.

II. Claims 15-24, drawn to a method for "producing a recombinant vector comprising isolated DNA encoding a product of interest", classified variously in class 435, subclass 91.1, 91.4, 91.21, 127.3.

III. Claims 25-26, drawn to a product described as a "cell transformed by a recombinant vector comprising isolated DNA encoding a snRNA", classified in class 435, subclass 320.1.

IV. Claims 27-28, drawn to a product described as a "cell library comprising cells transformed by a plurality of recombinant vectors", classified variously in class 435, DIG 22; class 435, DIG 23.

V. Claim 29, drawn to a method for "identifying a modification of a snRNA which suppresses transcription of a transcription product in a cell", classified variously class 435, subclass 4, 5, 6, and 7.1.

VI. Claim 30, drawn to a method for "suppressing expression of a transcription product in a cell", classified variously in class 514, subclass 44; class 435, subclass 375, 440+.

VII. Claim 31, drawn to a method for "delivering an antisense targeting sequence into a cell nucleus", classified variously in class 435, subclass 455, 375.

2. The inventions are distinct, each from the other because of the following reasons:

3. Groups I and III-IV represent patentably distinct products. Groups I and III-IV represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. For example, Group IV is drawn to a "library", which requires different reagents and/or materials than Groups I and III. Likewise, Group I is drawn to "isolated DNA", which does not require "cells" like the products of Groups III and IV. Therefore, art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Consequently, Groups I, III and IV have different issues regarding patentability and enablement and represent patentably distinct subject matter.

4. Groups II and V-VII represent separate and patentably distinct methods. The methods are distinct because they use different steps, require different reagents and/or will produce different results. In the instant case, Group VII requires method steps for "delivering an antisense targeting sequence into a cell nucleus", which are steps that are not required by the other Groups. Likewise, Group VI requires method steps for "suppressing expression of a transcription product in a cell", which are steps that are not required by the other Groups. Furthermore, Group V requires method steps for "identifying a modification of a snRNA which suppresses transcription of a transcription product in a cell", which are steps that are not required by the other Groups. Therefore, Groups II and V-VII have different issues regarding patentability and enablement and represent patentably distinct subject matter.

5. Groups I and III-IV and Groups II and V-VII represent separate and patentably distinct inventions. Groups I and III-IV are drawn to different products (see above) and Groups II and V-VII are drawn to different methods. Therefore, the Groups that describe these products and methods have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Each group will support separate patents.

6. However, if applicant were to argue that Groups I and II are somehow related as process of making and product made, the inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, (2) the product as claimed can be made by another materially different process e.g., the "recombinant vector" can be via homologous recombination.

7. Furthermore, if applicant were to argue that any of the Group I and any of Groups V-VII were somehow related as product and process of use, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, (1) the product as claimed (i.e., Groups I) can be used in materially different process of using that product (MPEP § 806.05(h)), for example, the products (i.e., Groups I) could be used in any of the patentably distinct methods provided by applicant (i.e., Groups V-VII).

8. Likewise, if applicant were to argue that Groups III and IV are somehow related to any of Groups V-VII as product and process of use, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, (1)

the product as claimed (i.e., Groups III or IV) can be used in materially different process of using that product (MPEP § 806.05(h)), for example, the products (i.e., Groups III or IV) could be used in any of the patentably distinct methods provided by applicant (i.e., Groups V or VI or VII).

9. These inventions have acquired a separate status in the art as shown by their different classification (see paragraph 1) and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

10. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-VII. Election is required as follows.

11. If applicant elects the invention of Group I, applicant is required to elect from the following patentably distinct species. Claim 1 is generic.

Subgroup 1: Species of snRNA (see claim 1)

Applicant must elect, for the purposes of search, a ***single species*** of snRNA e.g., U1 (see claim 3).

Subgroup 2: Species of recombinant vector (see claim 1)

Applicant must elect, for the purposes of search, a ***single species*** of recombinant vector e.g., pcDNAA3.1Zeo+ (see specification, page 10, line 19).

Subgroup 3: Species of modification (see claim 1)

Applicant must elect, for the purposes of search, a ***single species*** modification e.g., single nucleotide is modified (see claim 7).

Subgroup 4: Species of restriction site (see claim 9)

Applicant must elect, for the purposes of search, a ***single species*** restriction site e.g., Bae1 restriction fragment (see claim 9).

Subgroup 5: Species of insertion site sequences (see claim 9)

Applicant must elect, for the purposes of search, a ***single species*** insertion site sequences e.g., SEQ ID NO: 2 and SEQ ID NO:3 (see claim 11).

12. If applicant elects the invention of Group II, applicant is required to elect from the following patentably distinct species. Claim 15 is generic.

Subgroup 1: Species of snRNA (see claim 15)

Applicant must elect, for the purposes of search, a ***single species*** of snRNA e.g., U1 (see claim 17).

Subgroup 2: Species of recombinant vector (see claim 15)

Applicant must elect, for the purposes of search, a ***single species*** of recombinant vector e.g., pcDNAA3.1Zeo+ (see specification, page 10, line 19).

Subgroup 3: Species of modification (see claim 15)

Applicant must elect, for the purposes of search, a ***single species*** modification e.g., single nucleotide is modified (see claim 7).

Subgroup 4: Species of restriction site (see claim 15)

Applicant must elect, for the purposes of search, a ***single species*** restriction site e.g., Bae1 restriction fragment (see claim 23).

Subgroup 5: Species of insertion site sequences (see claim 24)

Applicant must elect, for the purposes of search, a ***single species*** insertion site sequences e.g., SEQ ID NO: 2 and SEQ ID NO:3 (see claim 11).

13. If applicant elects the invention of Groups III-IV, applicant is required to elect from the following patentably distinct species. Claim 25 is generic for Group III and Claim 27 is generic for Group IV.

Subgroup 1: Species of snRNA (see claim 25)

Applicant must elect, for the purposes of search, a ***single species*** of snRNA e.g., U1 (see claim 17).

Subgroup 2: Species of recombinant vector (see claim 25)

Applicant must elect, for the purposes of search, a ***single species*** of recombinant vector e.g., pcDNAA3.1Zeo+ (see specification, page 10, line 19).

Subgroup 3: Species of cell (see claim 25)

Applicant must elect, for the purposes of search, a ***single species*** restriction site e.g., mammaalian (see claim 26).

Subgroup 4: Species of restriction site (see claim 27)

Applicant must elect, for the purposes of search, a ***single species*** restriction site e.g., Bae1 restriction fragment (see claim 23).

Subgroup 5: Species of insertion site sequences (see claim 27)

Applicant must elect, for the purposes of search, a ***single species*** insertion site sequences e.g., SEQ ID NO: 2 and SEQ ID NO:3 (see claim 11).

14. If applicant elects the inventions of Groups V, applicant is required to elect from the following patentably distinct species. Claim 29 is generic.

Subgroup 1: Species of snRNA (see claims 29)

Applicant must elect, for the purposes of search, a ***single species*** of snRNA e.g., U1 (see claim 17).

Subgroup 2: Species of recombinant vector (see claims 29)

Applicant must elect, for the purposes of search, a ***single species*** of recombinant vector e.g., pcDNAA3.1Zeo+ (see specification, page 10, line 19).

Subgroup 3: Species of cell (see claims 29)

Applicant must elect, for the purposes of search, a ***single species*** cell e.g., mammalian (see claim 26).

Subgroup 4: Species of restriction site (see claims 29)

Applicant must elect, for the purposes of search, a ***single species*** restriction site e.g., Bae1 restriction fragment (see claim 23).

Subgroup 5: Species of insertion site sequences (see claims 29)

Applicant must elect, for the purposes of search, a ***single species*** insertion site sequences e.g., SEQ ID NO: 2 and SEQ ID NO:3 (see claim 11).

Subgroup 6: Species of conditions suitable for delivery of the snRNA into the cell (see claims 29)

Applicant must elect, for the purposes of search, a ***single species*** of conditions suitable for delivery of the snRNA into the cell (see specification , Examples).

Subgroup 7: Species of method for determining a base level of transcription (see claims 29)

Applicant must elect, for the purposes of search, a ***single species*** of method for determining a base level of transcription (see specification, Examples).

15. If applicant elects the inventions of Groups VI, applicant is required to elect from the following patentably distinct species. Claim 30 is generic.

Subgroup 1: Species of snRNA (see claims 30)

Applicant must elect, for the purposes of search, a ***single species*** of snRNA e.g., U1 (see claim 17).

Subgroup 2: Species of recombinant vector (see claims 30)

Applicant must elect, for the purposes of search, a ***single species*** of recombinant vector e.g., pcDNAA3.1Zeo+ (see specification, page 10, line 19).

Subgroup 3: Species of cell (see claims 30)

Applicant must elect, for the purposes of search, a ***single species*** cell e.g., mammalian (see claim 26).

Subgroup 4: Species of restriction site (see claims 30)

Applicant must elect, for the purposes of search, a ***single species*** restriction site e.g., Bae1 restriction fragment (see claim 23).

Subgroup 5: Species of insertion site sequences (see claims 30)

Applicant must elect, for the purposes of search, a ***single species*** insertion site sequences e.g., SEQ ID NO: 2 and SEQ ID NO:3 (see claim 11).

Subgroup 6: Species of conditions suitable for delivery of the snRNA into the cell (see claims 30)

Applicant must elect, for the purposes of search, a ***single species*** of conditions suitable for delivery of the snRNA into the cell (see specification , Examples).

16. If applicant elects the inventions of Groups VII, applicant is required to elect from the following patentably distinct species. Claim 31 is generic.

Subgroup 1: Species of snRNA (see claims 31)

Applicant must elect, for the purposes of search, a ***single species*** of snRNA e.g., U1 (see claim 17).

Subgroup 2: Species of recombinant vector (see claims 31)

Applicant must elect, for the purposes of search, a ***single species*** of recombinant vector e.g., pcDNAA3.1Zeo+ (see specification, page 10, line 19).

Subgroup 3: Species of cell (see claims 31)

Applicant must elect, for the purposes of search, a ***single species*** cell e.g., mammalian (see claim 26).

Subgroup 4: Species of restriction site (see claims 31)

Applicant must elect, for the purposes of search, a ***single species*** restriction site e.g., Bae1 restriction fragment (see claim 23).

Subgroup 5: Species of insertion site sequences (see claims 31)

Applicant must elect, for the purposes of search, a ***single species*** insertion site sequences e.g., SEQ ID NO: 2 and SEQ ID NO:3 (see claim 11).

Subgroup 6: Species of conditions suitable for delivery of the snRNA into the cell (see claims 31)

Applicant must elect, for the purposes of search, a ***single species*** of conditions suitable for delivery of the snRNA into the cell (see specification , Examples).

17. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

18. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

19. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a a rejection under 35 U.S.C. 103(a) of the other invention.

20. Applicant is advised that a reply to this requirement ***must include an identification of the species that is elected consonant with this requirement***, ***and a listing of all claims readable thereon, including any claims subsequently added***. An argument that a claim is allowable or that all claims are generic is considered ***nonresponsive*** unless accompanied by an election.

21. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

22. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

23. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

24. Applicant is also reminded that a 1 – month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D.
February 10, 2003

BENNETT CELSA
PRIMARY EXAMINER